

Thank you for giving me the opportunity to send my comments on your draft. I am the chair of our IRB. We have a conflict of interest policy, a conflict of interest committee and have had some experience with working out conflicts so I think I have developed a feel for some of the problems.

The area that I am concerned about is section 1.4 in which an annual disclosure statement would be requested from the IRB including its staff. This would require a disclosure of all financial interests in any area that might be expected to appear in the IRB office. This is a more extensive disclosure than the researchers are asked for since the researchers are only asked to disclose about their particular project. I think that this extensive disclosure is unnecessary, is an intrusion of the members' privacy and would make it more difficult to find members for the IRB and in particular those to serve as community members. In addition it would greatly add to the work load because someone would have to make sure we obtained a new form annually from each IRB member, would have to review these disclosure forms every month before the meeting and before any reviews were done. All of this would have to be documented. I question the usefulness of including the IRB staff in this disclosure process because I do not see how their conflicts if indeed they had any, could possibly affect the outcome of the IRB review. The staff acts as secretaries and if they needed to make these disclosures then the researchers' secretaries also should make such disclosures.

Under section 3.1 you have outlined a more reasonable method for identifying members who might have a conflict. This is the method that we use. We have the sponsor of the research indicated in bold type on the agenda so members can easily note it. We have had the full cooperation of our members with this system.

Thank you.

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